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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,870	11/15/2001	Robin R. Miles	IL-10406B	1309

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EXAMINER	
PADMANABHAN, KARTIC	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,870	MILES ET AL.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/15/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 2/27/04 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 09/737,927 has been reviewed and is NOT accepted.

2. The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because:

> The application/patent being disclaimed has been improperly identified since the number used to identify the application being disclaimed is incorrect. The correct number is 09/738,927.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 is rejected as vague and indefinite for the recitation of "allowing pathogens to bind to the antibodies" because it is unclear to which antibodies the pathogens bind. Do they bind to the antibodies on the electrodes, or on the beads?

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 4, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stetter et al. (US Pat. 5,567,301) in view of Pyle et al. (US Pat. 5,821,066).

Stetter et al. teach a biosensor comprising two spaced metal electrodes, wherein at least one antibody is disposed on and/or between the two electrodes. The sensor also comprises impedance detection means for measuring the impedance between the two electrodes (cols. 3-4). Since figure 2 shows the impedance as a function of the AC frequency, the presence of an AC power source for the production of an electric field across the electrodes is inherent. In addition, since the sensor of the reference is used for the determination of analytes in a liquid, the positioning of the electrodes is interpreted as being on a surface of a fluidic channel, as a fluidic

channel is interpreted as any surface on which a fluid can travel. However, the reference does not teach antibody-coated beads.

Pyle et al. teach a method for the detection of microorganisms, wherein magnetic beads coated with various antibodies may be used with detection methods such as impedance measurements for greater testing efficiency.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibody-coated beads of Pyle et al. with the method of Stetter et al. because Pyle et al. teach that these beads are frequently used in impedance measurements and increase test efficiency. Further, by using these beads to bind pathogen already bound to the electrode surface, an even greater change in impedance will be observed, thereby providing very reliable assay results.

10. Claims 1, 4, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clerc (US Pat. 6,133,046) in view of Pyle et al. (US Pat. 5,821,066).

Clerc teaches an apparatus for detecting an analyte in a sample comprising at least one mobile electrode and one fixed electrode opposite the mobile electrode disposed within a fluidic channel. Both electrodes may be coated with a ligand, wherein the ligand may be an antibody to the analyte of interest. The device also comprises means for measuring the impedance between the electrodes (cols. 2-3). The application of voltage to the electrodes creates a magnetic field or electric filed around the apparatus. The apparatus may also comprise a second pair of spaced electrodes (col. 10). However, the reference does not teach antibody-coated beads.

Pyle et al. teach a method for the detection of microorganisms, wherein magnetic beads coated with various antibodies may be used with detection methods such as impedance measurements for greater testing efficiency.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibody-coated beads of Pyle et al. with the method of Clerc et al. because Pyle et al. teach that these beads are frequently used in impedance measurements and increase test efficiency. Further, by using these beads to bind pathogen already bound to the electrode surface, an even greater change in impedance will be observed, thereby providing very reliable assay results.

11. Claims 1, 3-7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vadgama et al. (WO 98/19153) in view of Pyle et al. (US Pat. 5,821,066).

Vadgama et al. teach a sensor comprising an immobilized affinity component associated with a conducting polymer, such that interaction of the target analyte with the affinity component induces a change in a detectable electrical property. The sensor of the reference also comprises means for applying an AC signal to the polymer and means for detecting the impedance of the polymer (page 2). The affinity component of the sensor may be an antibody. The polymer may be in the form of a layer bridging two electrodes between which the impedance is measured. The two electrodes together may define an interdigitated electrode assembly (page 3). It is inherent that the electrode assembly is located on a surface of a fluid channel for reasons discussed previously. However, the reference does not teach antibody-coated beads.

Pyle et al. teach a method for the detection of microorganisms, wherein magnetic beads coated with various antibodies may be used with detection methods such as impedance measurements for greater testing efficiency.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibody-coated beads of Pyle et al. with the method of Vadgama et al. because Pyle et al. teach that these beads are frequently used in impedance measurements and increase test efficiency. Further, by using these beads to bind pathogen already bound to the electrode surface, an even greater change in impedance will be observed, thereby providing very reliable assay results. It would also have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a plurality of mixer/amplifier assemblies with the modified method of Van Gerwen et al. and Pyle et al. One would have been motivated to do so because such assemblies were well known in the art at the time of the invention and would have facilitated the concurrent measurement of multiple impedance signals in various phases and at different angles.

12. Claims 1, 3-7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Gerwen et al. (WO 97/21094) in view of Pyle et al. (US Pat. 5,821.066).

Van Gerwen et al. teach an impedimetric detection system comprising an insulating layer with a plurality of interspersed channels therein. A metal coating is applied to one of the two opposite side walls of each channel and on top of the dielectric layer in between said channels, thereby forming an impedimetric device. Probes are applied to either the insulating part of the channels or to the surface of the electrodes or both. The device also comprises means for applying a voltage on the metal coatings and measuring the impedance between the electrodes.

The sensor of the reference also has an interdigitated electrode structure. The probes of the device include antibodies (page 5 and figures 1-7). When an electric signal is applied (voltage or current), an electric field arises. If the analyte is present in the solution tested, it will be bound to the probe on the electrode surface, resulting in a change in impedance, which is then quantified (page 15). It is inherent that the means for producing the electric field is an AC or DC power supply. However, the reference does not teach antibody-coated beads.

Pyle et al. teach a method for the detection of microorganisms, wherein magnetic beads coated with various antibodies may be used with detection methods such as impedance measurements for greater testing efficiency.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibody-coated beads of Pyle et al. with the method of Van Gerwen et al. because Pyle et al. teach that these beads are frequently used in impedance measurements and increase test efficiency. Further, by using these beads to bind pathogen already bound to the electrode surface, an even greater change in impedance will be observed, thereby providing very reliable assay results. It would also have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a plurality of mixer/amplifier assemblies with the modified method of Van Gerwen et al. and Pyle et al. One would have been motivated to do so because such assemblies were well known in the art at the time of the invention and would have facilitated the concurrent measurement of multiple impedance signals in various phases and at different angles.

13. Claims 1, 3-4, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Pat. 5,194,133) in view of Kipling et al. (US Pat. 5,374,521) and Pyle et al. (US Pat. 5,821,066).

Clark et al. teach sensor devices and methods comprising pairs of sensing electrodes that are spaced apart along the walls of a channel that has been micromachined in a surface of a substrate (abstract). The channel walls may be coated with a biological substance, such as an enzyme (col. 1). The electrodes may be amperometric enzyme electrodes (Col. 3, lines 48-50). The sensors of the reference may be used to measure impedance between electrodes (col. 5, lines 50-55). A DC pulse may be used generate the electric field (col. 5, lines 60-65). The reference also teaches a plurality of signal generators and a plurality of amplifier/mixer assemblies (Figure 6). The reference does not teach antibodies located on the electrodes.

Kipling et al. teach a sensor comprising a pair of spaced electrodes that may both have a coating attached thereto (col. 1). A receptor will be attached to the coating on the electrodes, and the receptor may any biomolecule, including antibodies (col. 5). A voltage is applied between the electrodes, which makes it inherent that there is a means for applying this voltage to create an electric field (col. 3). The impedance between the electrodes is one of the parameters that can be determined with the sensor of the reference (col. 5). It is further inherent that the electric field is produced by an AC or DC power supply because these power supplies are generally used to apply voltages at various frequencies. However, the reference does not teach the use of antibody-coated beads.

Pyle et al. teach a method for the detection of microorganisms, wherein magnetic beads coated with various antibodies may be used with detection methods such as impedance measurements for greater testing efficiency.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibodies on the surfaces of the electrode as taught by Kipling et al. with the device of Clark et al. because Kipling teaches that any number of biomolecules can be used on the electrode surface. Therefore, depending on the analyte one wishes to detect, one would have known that a number of receptors could have been placed on the electrodes of Clark et al. with a reasonable expectation of success. Further, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibody-coated beads of Pyle et al. with the modified method of Clark et al. and Kipling et al. because Pyle et al. teach that these beads are frequently used in impedance measurements and increase test efficiency. Further, by using these beads to bind pathogen already bound to the electrode surface, an even greater change in impedance will be observed, thereby providing very reliable assay results. It would have also been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a plurality of mixer/amplifier assemblies with the modified method of Clark et al., Kipling et al., and Pyle et al. because such assemblies were well known in the art at the time of the invention and would have facilitated the concurrent measurement of multiple impedance signals in various phases and at different angles.

14. Claims 5, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Pat. 5,194,133) in view of Kipling et al. (US Pat. 5,374,521) and Pyle et al. (US Pat.

5,821,066) as applied to claims 1, 3-4, 7, and 9 above, and further in view of Taylor et al. (US Pat. 5,001,048).

Clark et al., Kipling et al., and Pyle et al. teach modified sensing methods, as discussed above. However, the references do not teach the use of reference electrodes or an interdigitated electrode assembly.

Taylor et al. teach an electrical biosensor for analyte determination. In one embodiment, a single chip design is used, wherein the transducer is a quartz or glass substrate containing two terminal interdigitated electrodes. A receptor (which may be an antibody) containing membrane is in contact with the electrodes. A current is applied across the electrodes creating an electric field, such that a change in impedance results upon binding of an analyte to its receptor. The impedance is measured and is indicative of analyte concentration in the sample. In another embodiment, a double chip design may be used. This biosensor includes a non-receptor (reference) membrane and a receptor containing membrane, wherein the membranes are attached to different electrode surfaces, and impedance measured from control membrane is considered as a background signal. A barrier, which may be comprised of an insulator, is located between the reference and receptor-containing electrode to inhibit current flow between the two surfaces. It is once again inherent that the power supply is AC or DC.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the reference electrodes and insulating layer, as well as the interdigitated electrode assembly of Taylor et al. with the modified method of Clark et al., Kipling et al., and Pyle et al. One would have been motivated to use a reference electrode in an insulating layer to determine a background signal, wherein a difference from background can be used as an

indication of the analyte of interest. Further, an insulator provides the advantage of preventing current flow between the reference electrode and sensor electrode, which results in a contamination of assay results. It would have also been obvious to use an interdigitated electrode assembly because Clark et al. state that a number of electrode configurations can be used with the device of their reference. Further, the configuration depicted in figure 4 of the reference resembles an interdigitated assembly, and one would expect such a configuration to work with their sensor.

15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Gerwen et al. (WO 97/21094), Vadgama et al. (WO 98/19153), Stetter et al. (US Pat. 5,567,301), or Clerc et al. (US Pat. 6,133,046) in view of Pyle et al. (US Pat. 5,821,066) and further in view of Taylor et al. (US Pat. 5,001,048).

Van Gerwen et al., Vadgama et al., Stetter et al., Clerc et al., and Pyle et al. teach modified sensing methods, as previously discussed. However, the references do not teach reference electrodes or insulation.

Taylor et al. teach an electrical biosensor for analyte determination. In one embodiment, a single chip design is used, wherein the transducer is a quartz or glass substrate containing two terminal interdigitated electrodes. A receptor (which may be an antibody) containing membrane is in contact with the electrodes. A current is applied across the electrodes creating an electric field, such that a change in impedance results upon binding of an analyte to its receptor. The impedance is measured and is indicative of analyte concentration in the sample. In another embodiment, a double chip design may be used. This biosensor includes a non-receptor (reference) membrane and a receptor containing membrane, wherein the membranes are attached

to different electrode surfaces, and impedance measured from control membrane is considered as a background signal. A barrier, which may be comprised of an insulator, is located between the reference and receptor-containing electrode to inhibit current flow between the two surfaces. It is once again inherent that the power supply is AC or DC.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the reference electrodes and insulating layer of Taylor et al. with the modified method of Van Gerwen et al., Vadgama et al., Stetter et al. or Clerc et al. and Pyle et al. because the use a reference electrode in an insulating layer allows the determination of a background signal, wherein a difference from background can be used as an indication of the analyte of interest. Further, an insulator provides the advantage of preventing current flow between the reference electrode and sensor electrode, which results in a contamination of assay results.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1 and 3-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-15 of copending Application No. 09/738,927 (US 2002/0070114 A1) in view of Kipling et al. (US Pat. 5,374,521).

Miles teaches a method for detecting the presence of pathogens trapped in an electric field, comprising a fluidic channel, at least one pair of interdigitated electrodes positioned in the surface of the channel, an AC power source for applying a voltage across the electrodes, and means for measuring the impedance between electrodes as an indication of pathogen presence. The device also comprises a plurality of signal generators, amplifiers and mixers (See claims). However, the reference does not teach antibodies immobilized on the electrodes.

Kipling et al. teach a sensor comprising a pair of spaced electrodes that may both have a coating attached thereto (col. 1). A receptor will be attached to the coating on the electrodes, and the receptor may any biomolecule, including antibodies (col. 5). A voltage is applied between the electrodes, which makes it inherent that there is a means for applying this voltage to create an electric field (col. 3). The impedance between the electrodes is one of the parameters that can be determined with the sensor of the reference (col. 5). It is further inherent that the electric field is

produced by an AC or DC power supply because these power supplies are generally used to apply voltages at various frequencies.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the antibodies on the surfaces of the electrode as taught by Kipling et al. with the method of Miles because Kipling teaches that any number of biomolecules can be used on the electrode surface. Therefore, depending on the analyte one wishes to detect, one would have known that a number of receptors could have been placed on the electrodes of Miles with a reasonable expectation of success.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

18. Applicant's arguments have been fully considered and are persuasive to overcome the 102 rejections of the prior office action, as well as the 103 rejections using Miles or Krulevitch, as applicant has stated that the reference and the present application have a common assignee. However, they are not persuasive to overcome the remaining rejections present in this office action.

19. Applicant's arguments that the references previously applied under 35 USC 102 lack antibody coated beads are moot, as these reference have now been applied under 35 USC 103. This same rationale also holds true for the 103 rejection over Clark and Kipling, which references have now also been combined with Pyle et al.

20. Applicant also argues that the various combination of references fails to teach directing a sample with pathogens, antibodies, and beads past the spaced electrodes; however, applicant has simply made this conclusion without any rationale, which is prima facie unconvincing.

However, insofar as this position merits discussion, the various combination of references teaches flowing the sample solution past the electrodes to measure impedance. When combined with Pyle's teaching of using antibody-coated beads, these beads would necessarily be in the solution to bind the pathogens, which solution would still have to flow past the electrodes for impedance to be measured.

21. The double patenting rejection of the prior office action is maintained, as applicant has attempted to disclaim the wrong application.

Conclusion

Claims 1 and 3-9 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

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03/20/04